Case Number:	CM14-0036528		
Date Assigned:	03/28/2014	**Date of Injury:**	08/20/2010
Decision Date:	05/08/2014	**UR Denial Date:**	03/17/2014
Priority:	Standard	**Application Received:**	03/25/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Occupational Medicine and is licensed to practice in California and Oklahoma. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The patient is a 51-year-old male who was injured on 08/20/2010. The mechanism of injury is unknown. He complains of neck and low back pain. Prior treatment history has included myofascial release, trigger points injections, epidural injections and other therapies. Medications as of 02/12/2014 include: (Pain is rated at 4/10 in the low back, 3/10 in the leg and 5/10 in the neck) Lisinopril, Fentanyl, Oxycodone, Cymbalta, Flexeril, Promethazine, Ambien CR. Medications as of 10/23/2013 include: (Pain is rated at 6/10 in the low back and 8/10 in the neck) Lisinopril, Fentanyl, Oxycodone, Cymbalta, Flexeril, Promethazine, Ambien CR. Progress Report dated 02/12/2014 indicated the patient had complaints of pain in the low back, leg, and in the neck. The patient was having an exacerbation of symptoms and suffers from chronic pain syndrome, chronic discogenic pain syndrome, and secondary myofascial syndrome. Physical findings revealed the patient was alert and oriented to person, time, and place. Cranial nerves II-XII were intact. Motor is without focal changes. He has no gait instability. He has trigger points noted in the bilateral levator and rhomboid groups. The lumbar spine revealed no spasm; JAMAR revealed 80-pound grip strength on the right and 88 on the left. Progress note dated 10/23/2013 stated the patient demonstrated low testosterone levels. He has opioids related hypogonadism. His testosterone was 266 on 09/14/2013 and normal is 350-1190. The patient has been taking Fentanyl as a timed contingent opioids and oxycodone for breakthrough pain. He is also experiencing symptoms with increased fatigue. It is believed that the testosterone replacement will help considerably. On physical exam, there was no gait instability. The lumbar spine revealed trigger points in the bilateral gluteus medius and piriformis groups. JAMAR revealed 55-pound grip strength on the right and 62 on the left. The treatment plan involves Fentanyl 25, Percocet for breakthrough pain and Cymbalta.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

TESTOSTERONE 200MG 1X PER WEEK: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone Replacement For Hypogonadism (Related To Opioids).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Testosterone Replacement For Hypogonadism Page(s): 110-111.

Decision rationale: CA MTUS detail guideline for testosterone replacement: "Recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. Hypogonadism has been noted in patients receiving intrathecal opioids and long-term high dose opioids. Routine testing of testosterone levels in men taking opioids is not recommended; however, an endocrine evaluation and/or testosterone levels should be considered in men who are taking long term, high dose oral opioids or intrathecal opioids and who exhibit symptoms or signs of hypogonadism, such as gynecomastia. If needed, testosterone replacement should be done by a physician with special knowledge in this field given the potential side effects such as hepatomas. There are multiple delivery mechanisms for testosterone. Hypogonadism secondary to opiates appears to be central, although the exact mechanism has not been determined. The evidence on testosterone levels in long-term opioid users is not randomized or double-blinded, but there are studies that show that there is an increased incidence of hypogonadism in people taking opioids, either intrathecal or oral. There is also a body of literature showing that improvement in strength and other function in those who are testosterone deficient who receive replacement. (Nakazawa, 2006) (Page, 2005) (Rajagopal, 2004). This appears to be more pronounced than in patients taking oral opiates than in patients receiving intrathecal opioids, and this difference seems to be related to differences in absorption. Hypogonadism secondary to opiates appears to be central, although the exact mechanism has not been determined. (Abs, 2000) (Roberts, 2002) (Roberts, 2000) Etiology of decreased sexual function, a symptom of hypogonadism, is confounded by several factors including the following: (1) The role of chronic pain itself on sexual function; (2) The natural occurrence of decreased testosterone that occurs with aging; (3) The documented side effect of decreased sexual function that is common with other medications used to treat pain (SSRIs, tricyclic antidepressants, and certain anti-epilepsy drugs); & (4) The role of comorbid conditions such as diabetes, hypertension, and vascular disease in erectile dysfunction. There is little information in peer-reviewed literature as to how to treat opioid induced androgen deficiency. Long-term safety data of testosterone replacement (overall): Not available. Cardiovascular risk: There have been no large randomized controlled trials to evaluate the cardiovascular risk associated with long-term testosterone use, although current studies weakly support that there is no association with important cardiovascular effects. (Haddad 2007) Osteoporosis: The extent to which testosterone can prevent and treat osteoporosis remains unclear. (Tracz 2006) (Isidori, 2005) Sexual function: Current trials of testosterone replacement in patients with documented low testosterone levels have shown a moderate non-significant and inconsistent effect of testosterone on erectile function, a large effect on libido, and no significant effect on overall sexual satisfaction. (Bolona, 2007) (Isidori, 2005) The one study (sponsored by the drug company) that has evaluated the use of testosterone replacement in patients with opioid-induced androgen deficiency, measured morning serum free testosterone levels and PSA prior to replacement. This study did not include patients taking antidepressants. (Daniell, 2006). "The medical records that were sent to me do not demonstrate how hypogonadism has been established in this patient. Additionally the dose seems

high given the active issues with this patient. Based on the available records and guidelines referenced above, the request is not medically necessary.